



The Advertising Standards Authority of South Africa

(Association incorporated under Section 21)

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**To:** Mr Anthony Brink  
Dr Rath Health Foundation

**Fax:** (021) 441 2101

**From:** Ms Gail Schimmel

**Date:** 9 March 2005

**Reference:** DR RATH HEALTH FOUNDATION / TAC & ANOTHER / 1861

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Dear Mr Brink

We refer to the above matter and enclose herewith a copy of the ASA Directorate Ruling.

Yours faithfully

**THE ADVERTISING STANDARDS AUTHORITY OF SOUTH AFRICA**

PP   
GAIL SCHIMMEL

**SENIOR CONSULTANT: DISPUTE RESOLUTION**  
lcvdb

Encl. ASA Directorate Ruling (11 pages)



## The Advertising Standards Authority of South Africa

(Incorporated in South Africa)

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### RULING OF THE ASA DIRECTORATE

In the matter between:

**TREATMENT ACTION CAMPAIGN (TAC)**

**FIRST COMPLAINANT**

**GEORGE STACEY**

**SECOND COMPLAINANT**

and

**DR RATH HEALTH FOUNDATION AFRICA**

**RESPONDENT**

9 March 2005

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#### DR RATH HEALTH FOUNDATION / TAC & ANOTHER / 1881

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Consumer complaints were lodged against a Dr Rath Health Foundation Africa print advertisement that appeared in the Mail & Guardian on 26 November 2004.

The advertisement is headed "Why should South Africans continue to be poisoned with AZT? THERE'S A NATURAL ANSWER TO AIDS" and contains a number of claims regarding this topic.

#### COMPLAINTS

In essence, the complainants submit that the advertisement breaches the Code in the following respects:

- It exaggerates the efficacy of multivitamins in "treating" AIDS.
- It deliberately misleads consumers about zidovudine (AZT).
- It deliberately misleads consumers about nevirapine (NVP).
- It deliberately misleads the public about the MCC.

The first complainant requested sanctions.

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Directors DE Baloyi (Chairperson) IRB Shepherd (Vice Chairperson) DA Bekker (Executive Director) RA Abrahams DA Bailie SF du Plessis (R May) NV Nkomo

## RELEVANT CLAUSES OF THE CODE OF ADVERTISING PRACTICE

The first complainant identified the following clauses of the Code as relevant:

- Section II, Clause 2 – Honesty
- Section II, Clause 4.1 – Substantiation
- Section II, Clause 4.2.1 – Misleading claims
- Section II, Clause 4.2.2 – Puffery
- Section II, Clause 4.2.3 – Hyperbole
- Section II, Clause 4.2.4 – Expert opinion
- Section II, Clause 4.2.5 – Statistics and scientific information
- Section II, Clause 4.2.6 – Headlines
- Section II, Clause 6 – Disparagement
- Section II, Clause 7 – Comparative advertising
- Section II, Clause 13 – Safety
- Appendix H – Advertising for over-the-counter medicines

In addition, in light of the second complainant's submissions, the following further clauses of the Code were taken into account:

- Section I, Clause 1.2 – Responsibility to the consumer
- Appendix A – Medicinal and related products and advertisements containing health claims
- Appendix F – References to diseases in advertising

## RESPONSE

The respondent addressed the ASA Directorate at length on the merits of the matter, and denied that the advertisement is in breach of the Code.

## ASA DIRECTORATE RULING

At a meeting held on 9 February 2005 the Directorate considered the relevant documentation submitted by the respective parties.

### Controversy

The treatment of HIV / AIDS is a highly controversial subject by its nature, and especially in light of the type of claims made in the advertisement.

Clause 2.4 of Section I states:

"To the extent that any advertisement:

- Expresses an opinion on a matter which is the subject of controversy; and

- That controversy involves issues within the areas, broadly defined, of public policy and practice, then that opinion shall not be subject to the provisions of the Code relating to misleading claims except that-

All advertisements which contain such controversial statements should:

- be readily recognisable as advertisements;
- cause no confusion as to the identity or status of advertiser;
- Whenever such information is not readily available state the advertiser's address and telephone number.\*

This clause creates certain requirements for a claim to amount to a "controversial statement". Once it has been established that the statement is controversial, the Directorate may not consider whether or not the claim is misleading. In other words, the claim can no longer be evaluated in terms of Clause 4.2.1 of Section II but can be considered in terms of the remaining clauses of the Code

For this reason, the Directorate will first consider whether or not each claim is acceptable in terms of the named clauses of the Code other than Clause 4.2.1 of Section II. Only if the claim is acceptable in terms of the other clauses, will it become necessary for the Directorate to determine whether or not the claim in question falls within the ambit of Clause 2.4 of Section I, in order to determine whether or not Clause 4.2.1 of Section II can be considered.

#### **Substantiation**

The respondent has lodged a bulky set of research in substantiation of its claims. The respondent's attention is drawn to Clause 4.1.4 of Section II which requires that "Documentary evidence... shall emanate from or be evaluated by a person/entity, which is independent, credible, and an expert in the particular field to which the claims relate and be acceptable to the ASA." The substantiation submitted is in the form of various research articles, extracts from websites and articles by the respondent's representatives. These have not been evaluated by an independent expert or entity as required by Clause 4.1 of Section II.

However, in so far as the advertisement refers to particular outcomes of particular studies, the ASA will have regard to the accuracy of same.

**The ASA wishes to clarify its role in this matter before proceeding on the merits:**

1. The ASA does not have the jurisdiction or ability to decide on the efficacy or safety of either of the treatments debated. This is the role of the Medicines Control Council (MCC).
2. The ASA's role is essentially to determine whether the information conveyed to the consumer is substantiated and conveyed within the restrictions imposed by the Code.

#### **Pharmaceutical Manufacturers Association of South Africa**

Finally, the ASA wishes to address a concern raised by the respondent that the Pharmaceutical Manufacturers Association of South Africa is a member of the ASA, and the influence that this will have on the ASA's decision. The respondent should note that member bodies of the ASA are not involved in the decision making process at Directorate level, and the alleged bias can therefore not arise in the current decision.

**Turning to the advertisement:**

**Headline: "Why should South Africans continue to be poisoned with AZT"**

The respondent has submitted that this is the only part of the advertisement that falls within the ambit of Clause 2.4 of Section I, and therefore should not be considered by the ASA. The restriction imposed by Clause 2.4 of Section I, however, only extends to misleading claims, as previously indicated.

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The Directorate is therefore called upon to first consider the other clauses of the Code. The claim in question relies on a factual assumption that "South Africans continue to be poisoned by AZT". The toxicity of AZT must therefore be substantiated.

As noted above, the respondent has submitted bulky substantiation, much of which appears to relate to potential toxicity of various treatments. However, Clause 4.1 of Section II calls upon the respondent to submit verification from an independent, credible expert in the relevant field.

As the respondent has failed to submit such verification of the claim, "South Africans continue to be poisoned with AZT", the claim is in breach of Clause 4.1 of Section II.

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim:** "On 1 July 2004, a landmark study by Harvard University was published in one of the world's leading medical journals, the *New England Journal of Medicine*, summed up the same day by the world's most influential and respected newspaper, the *New York Times*: 'The study found that daily doses of multivitamins slow down the disease and cut the risk of developing AIDS in half.'"

On careful reading of this statement in its entirety, one notes that the claim is not that the study found that "doses of multivitamins slow down the disease and cut the risk of developing AIDS in half" but that the *New York Times* summarised the study in this way.

The Directorate notes that the respondent has not provided a copy of the relevant article.

This aside, the overall impression of this claim is that the study has indeed made these findings. The hypothetical reasonable person would not understand that the *New York Times* may have misinterpreted or misquoted the study. The impact of the claim is therefore that the study in question made the cited findings.

The study in question *ex facie* found that, "Multivitamin supplements delay the progression of HIV disease and provide an effective, low-cost means of delaying the initiation of antiretroviral therapy in HIV-infected women." This appears to be different from implying that the study found that "daily doses of multivitamins slow down the disease and cut the risk of developing AIDS in half".

The claim, as communicated to the consumer, is therefore not supported by the documentation submitted, and is not substantiated in terms of Clause 4.1 of Section II.

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and

- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim:** "The question is why the people of South Africa have not been told about this. For actively promoting natural health approaches to AIDS, the South African government has continually been attacked by pharmaceutical interest groups and received no support at all from the medical establishment. The reason for this lack of support is obvious. Non-patentable natural therapies have very low profit margins, whereas patented synthetic pharmaceutical AIDS drugs are a multi-billion dollar business."

This paragraph in the advertisement states the opinion of the advertiser, and as a whole does not rely on any objectively substantiable statements of fact or figures. For this reason, the bulk of the paragraph does not fall within the ambit of Clauses 2, 4.1 or 4.2.5 of Section II.

The exception to this is the statement that, "Non-patentable natural therapies have very low profit margins" This is an objectively substantiable fact. The respondent has not put anything before the Directorate to illustrate the comparative costs of different therapies, and the Directorate is therefore unable to consider whether the statement correctly reflects the facts.

The statement, "Non-patentable natural therapies have very low profit margins" is therefore unsubstantiated in terms of Clause 4.1 of Section II.

Given the above finding:

- The claim must be withdrawn,
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide, and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

Turning to the remainder of the paragraph, the Directorate notes as follows:

Clauses 4.2.2 and 4.2.3 of Section II refer to potential defences rather than breaches; no expert opinion is expressed in terms of Clause 4.2.4 of Section II; the statement is not a headline in terms of Clause 4.2.6 of Section II; The statement does not refer to another product specifically and Clauses 6 and 7 of Section II therefore do not apply, and the statement does not directly advocate any potentially unsafe behaviour in terms of Clause 13 of Section II. Appendices A, H and F do not apply as the statement does not refer to any medicinal product or treatment that the respondent sells.

The statement therefore does not appear to breach any clauses of the Code, with the possible exception of Clause 4.2.1 of Section II and Clause 1.2 of Section I. The question of whether the statement is irresponsible and therefore in breach of Clause 1.2 of Section I is inherently tied to the question of whether or not the statement is misleading and the Directorate is unable to consider this clause in isolation from Clause 4.2.1 of Section II.

As the question is now whether or not the statement is misleading in terms of Clause 4.2.1 of Section II, the Directorate firstly has to consider whether or not the claim falls within the ambit of Clause 2.4 of Section I.

The first requirement of the clause is that the claim expresses an opinion on a subject of controversy. The Directorate is in no doubt that the treatment of Aids and in particular the role of the South African government therein, is controversial. As indicated above, the statement is also the opinion of the advertiser.

The second requirement is that the controversy concerns issues of public policy and practice. The respondent has, in this opinion, highlighted the ongoing public debate regarding the government's Aids policy. This clearly falls within the ambit of public policy and practice.

The claim therefore falls within the ambit of Clause 2.4 of Section I, and the Directorate is therefore unable to consider whether or not the opinion is misleading.

**Claim: "The Harvard study, conducted in Tanzania over a period of eight years, involved more than a thousand HIV-positive pregnant women. It was a placebo controlled and double blind trial conforming to the highest standards. The study showed that inexpensive multivitamin treatment is more effective in staying off disease among HIV-positive women than any toxic AIDS drug. (NEMJ 2004 Jul 1;351 (1): 23-32)"**

In considering whether or not this is substantiated, the ASA had regard to the contents of the actual study cited:

- It is correct that the study was in Tanzania.
- It is correct that the period of study was "eight years". The study states, "...starting in April 1995...until the end of the study in August 2003."
- It is correct that the study involved "more than a thousand HIV positive pregnant women". The exact figure is 1078.
- It is correct that the test was "placebo controlled and double blind."
- While the report on the test does not say that it conformed to the "highest standards", it appears to be a reasonable conclusion given the aforementioned and the respectability of the journal in question.

The claim in the advertisement concludes that, "The study showed that inexpensive multivitamin treatment is more effective...than any toxic AIDS drug."

The study, in fact, reached no conclusion in relation to the relative efficacy of various treatments, and the study did not use a drug using control group. The study also reached no conclusion relating to or made any reference to any "toxic AIDS drug".

While the advertiser may have drawn this conclusion from comparisons with other research it is incorrect to say that the "study showed" this.

**The claim is therefore unsubstantiated and in breach of Clause 4.1 of Section II.**

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide, and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim: "More than a decade ago, a study co-authored by two-time Nobel Prize winner Linus Pauling, published in another leading scientific journal, found that an optimal dose of vitamin C can block the replication of HIV by 99% (Proceedings of the National Academy of Sciences of the United States of America 1990 Sep;87 (18):7246-9)"**

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The study in question states, "In chronically infected cells expressing HIV at peak levels, ascorbate reduced the levels of extracellular reverse transcriptase activity (by > 99%)."

The communication of the advertisement is that Vitamin C has a 99% block on the replication of HIV in all cells. From the study it appears *ex facie* that this is only true, at best, for "chronically infected cells"

As blocking the HIV replication by 99% in a chronically infected cell has *ex facie* significantly different impact from blocking the replication of HIV by 99% in all cells, the communication is not substantiated.

**The claim is therefore unsubstantiated and in breach of Clause 4.1 of Section II.**

Given the above finding,

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim: "Every textbook of biochemistry recognises that vitamins and other micronutrients are the most decisive factor determining the optimum function of the immune system."**

The respondent has submitted, *inter alia*, extracts from a few relevant textbooks. The advertisement appears to draw conclusions from the material that the respondent has submitted. The ASA is not in a position to analyse and verify that the textbooks submitted support this conclusion. The ASA is also not in a position to accept that the submitted textbooks are "every text book", although the Directorate notes that it is extremely doubtful that this is the case.

As noted above, the respondent has submitted bulky substantiation, much of which appears to relate to the potential toxicity of various treatments. However, Clause 4.1 of Section II calls upon the respondent to submit verification from an independent, credible expert in the relevant field.

**As the respondent has failed to submit such verification of the claim, it is in breach of Clause 4.1 of Section II.**

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim: "Hundreds of studies have found that AZT is profoundly toxic to all cells of the human body, and particularly to the blood cells of our immune system."**



The respondent has submitted and referred to studies allegedly showing that AZT is toxic. However, the ASA notes that:

- The ASA does not have "hundreds" of such studies, or references thereto, before it.
- The ASA is not in a position to determine whether these studies support the statement "profoundly toxic"

As noted above, the respondent has submitted bulky substantiation, much of which appears to relate to potential toxicity of various treatments. However, Clause 4.1 of Section II calls upon the respondent to submit verification from an independent, credible expert in the relevant field.

**As the respondent has failed to submit such verification of the claim, it is in breach of Clause 4.1 of Section II.**

To this end, the ASA requests that should the respondent wish to submit further substantiation, it must have the hundreds of studies analysed by an independent expert in terms of Clause 4.1 of Section II, and have that expert verify that there are indeed at least over two hundred studies and that these studies all support the claim.

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim: "Numerous studies have found that children exposed to AZT in the womb suffer brain damage, neurological disorders, paralysis, spasticity, mental retardation, epilepsy, other serious diseases and early death."**

As noted above, the ASA is not in a position to evaluate whether the studies submitted by the respondent in support of this claim actually support the statement.

The respondent has submitted bulky substantiation, much of which appears to relate to potential toxicity of various treatments. However, Clause 4.1 of Section II calls upon the respondent to submit verification from an independent, credible expert in the relevant field.

**As the respondent has failed to submit such verification of the claim, it is in breach of Clause 4.1 of Section II.**

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim:** "Incredibly, two weeks after the publication of the Harvard study, the Medicines Control Council proposed new regulations that will effectively prevent free access to life-saving vitamin therapy and information about it, and recommended that HIV-positive women take AZT during their pregnancies."

While much of this statement is conjecture and opinion, it is based on an assumption that the MCC "proposed regulations will prevent access to life-saving vitamin therapy and information about it, and recommended that HIV positive women take AZT during their pregnancies." The Directorate notes that neither these proposed regulations nor any independent expert interpretation thereof are before it and the claim is therefore not substantiated in this respect.

The claim is therefore in breach of Clause 4.1 of Section II.

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

**Claim:** "On WORLD AIDS DAY the Treatment Information Group and the Dr Rath Health foundation ask the medical community and the people of South Africa:

- Do you want to continue being misled by the pharmaceutical industry and its front organizations to believe that exorbitantly expensive and highly toxic drugs like AZT and nevirapine are the answer to AIDS?
- Don't you think it's time to support the South African government and the traditional healers of South Africa and join our nationwide public information campaign based on natural science and medical truth?"

Again, the Directorate notes that the phrasing of this section of the advertisement takes the form of conjecture and opinion. However, the respondent has relied on certain substantiable statements as the basis for this opinion:

- "exorbitantly expensive and highly toxic drugs like AZT and nevirapine"
- "support the South African government and traditional healers"

As noted above, the respondent has submitted bulky substantiation, much of which appears to relate to potential toxicity of various treatments. However, Clause 4.1 of Section II calls upon the respondent to submit verification from an independent, credible expert in the relevant field. Such verification has not been submitted.

The claim "exorbitantly expensive and highly toxic drugs like AZT and nevirapine" is therefore unsubstantiated and in breach of Clause 4.1 of Section I.

The respondent has, in making these claims, created the impression that its campaign and philosophy is backed by the South African government and by the traditional healers of South Africa. There is nothing before the ASA to support this impression.

The claim "support the South African government and traditional healers" is therefore also in breach of Clause 4.1 of Section II.

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Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.

The picture of an AZT bottle and the claim, "This is a 25mg bottle of AZT supplied by Sigma-Aldrich for use in research laboratories. The label speaks for itself, GlaxoSmithKline recommends between 500 and 1500mg of AZT daily – twenty and sixty times the quantity that Sigma-Aldrich warns research workers could kill or severely injure them – alleging that AZT has extended and improved the quality of life of millions of people living with HIV/AIDS around the globe. Also that Glaxo Welcome (now GSK) are a reputable company. We do not lie to people."

Clause 6.1 of Section II states that, "Advertisements shall not attack, discredit or disparage other products, services, advertisers and advertisements directly or indirectly." Clause 6.2 recognises that, "Comparisons highlighting a weakness in an industry or product will not necessarily be regarded as disparaging when the information is factual and in the public interest."

The respondent has not addressed this issue head on in its submissions. The paragraph refers directly to AZT and GlaxoSmithKline. The implication is that AZT is toxic and that GlaxoSmithKline is in fact not 'reputable' and are recommending doses of AZT that could "kill or severely injure" people.

The Directorate is therefore in no doubt that the claims in this paragraph in particular, and the claims regarding the toxicity of AZT in general, disparage other AZT and GlaxoSmithKline.

As stated in Clause 6.2 of Section II, these claims would arguably be allowed if proven to be factual. In the matter at hand, however, as stated repeatedly above, insufficient substantiation has been submitted in respect of the claims. There is therefore no need for the Directorate to consider the implications of Clause 6.2 of Section II further at this stage.

The respondent's attention is also drawn to the provisions of Clause 7 of Section II for its own guidance.

**The claim is therefore in breach of Clauses 4.1 and 6 of Section II.**

Given the above finding:

- The claim must be withdrawn;
- The process to withdraw the advertising material must be actioned with immediate effect on receipt of ruling;
- The withdrawal of the advertising material must be completed within the deadlines stipulated by Clause 15.3 of the Procedural Guide; and
- The claim may not be used again in its current format until adequate substantiation is submitted, evaluated and a new ruling is made.


In light of the above findings, the Directorate finds it unnecessary to consider the remaining clauses at this point.

The Directorate wishes to specifically clarify the following:

- In Nampak / Kimberly-Clark/1400 the Advertising Industry Tribunal noted that, "The ASA has always held that principle requires offending advertising to be withdrawn from every medium in which it appears, notwithstanding that the complaint did not refer to that particular medium." Similarly, in this matter any ruling made in respect of the medium considered applies, in so far as the principle is relevant, to other mediums.
- Clause 3.1 of Section I states, "This Code is to be applied in the spirit, as well as the letter." This principle applies equally well to the reading of a ruling. Where the Directorate has ruled against a principle as stated in a particular claim, the principle as well as the specific claim may not be used again in future advertising.

**The complaint is upheld.**

The first complainant has requested sanctions in this matter. The complainants are therefore requested to comment on sanctions in light of this ruling and in terms of Clause 14 of the Procedural Guide, within 10 (ten) days of receipt of this ruling. Thereafter, the respondent will be given an opportunity to comment. The Directorate will then consider the matter in terms of Clause 8.5 of the Procedural Guide.

  
ON BEHALF OF THE ASA DIRECTORATE